

IN THE CHANCERY COURT FOR DAVIDSON COUNTY, TENNESSEE FOR THE TWENTIETH  
JUDICIAL DISTRICT AT NASHVILLE

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STATE OF TENNESSEE,  
Petitioner,

v.

KNOLL PHARMACEUTICAL,  
COMPANY, a foreign corporation,  
and BASF CORPORATION, a  
foreign corporation,

Respondents

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**PETITION**

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Paul G. Summers, Attorney General and Reporter for the State of Tennessee ("Attorney General"), files this Petition pursuant to Tenn. Code Ann. § 47-18-107 of the Tennessee Consumer Protection Act of 1977 ("the Act") and would respectfully show the Court as follows:

1. The Division of Consumer Affairs of the Tennessee Department of Commerce and Insurance ("the Division") and the Attorney General, acting pursuant to the Act, have investigated certain acts and practices of Knoll Pharmaceutical Company and BASF Corporation ("Respondents"). Upon completion of the investigation, the Division has determined that certain of Respondents' acts and practices, more specifically described in Paragraphs 2.0-2.17 of the Assurance of Voluntary Compliance, constitute unfair and deceptive acts or practices affecting the conduct of trade or commerce in the State of Tennessee in violation of Tenn. Code Ann. §§ 47-18-104(a) and (b)(27).
2. Based upon their investigation of Respondents, the Division and the Attorney General allege the following:

(A) Knoll Pharmaceutical Company is a New Jersey corporation engaged in, among other things, the discovery, development, manufacture and sale of pharmaceutical drugs. BASF is a Delaware corporation engaged in the business of , among other things, the manufacturing and selling of [sic] pharmaceutical drugs through its various subsidiaries, one of which is Knoll.

(B) Hypothyroidism is a medical condition in which a person's thyroid gland does not produce sufficient thyroid hormone. The common treatment for this condition is the prescription drug, levothyroxine sodium. Over eight million patients in the United States take levothyroxine sodium at any given time. Synthroid®, manufactured and sold by Knoll, is the dominant and most expensive brand of levothyroxine sodium product on the market.

(C) In or about May 1988, a predecessor company of Knoll contracted with Dr. Betty J. Dong, Pharm. D., at the University of California at San Francisco Medical School to design and perform a research study assessing the bioequivalence of Synthroid® and three other levothyroxine sodium products. In the opinion of the researchers who worked on the Dong Study, it demonstrated that all four levothyroxine sodium products were bioequivalent.

(D) Despite receiving this information in 1990 from Dr. Dong, Knoll (and its predecessors) failed to provide this information to governmental decision makers, including the FDA. Additionally, Respondents continued to advertise and represent that Synthroid® was superior to other levothyroxine sodium products or that no levothyroxine sodium product was equivalent to or useful in place of Synthroid®.

3. Respondents deny the allegations of Paragraph 2 (B-D).

4. Upon completion of its investigation, the Division requested the Attorney General to negotiate, and if possible to accept, an Assurance of Voluntary Compliance in accordance with the provisions set forth in Tenn. Code Ann. § 47-18-107.

5. The Attorney General entered into negotiations with Respondents and the parties have agreed to, and the Division has approved, the attached Assurance of Voluntary Compliance.

6. In accordance with the provisions of Tenn. Code Ann. § 47-18-107(c), the execution, delivery and filing of the Assurance does not constitute an admission of prior violation of the Act.

7. The Division, the Attorney General, and the Respondents, the parties who are primarily interested in the matters set forth in Paragraph 2 hereof, have jointly agreed to the Assurance of Voluntary Compliance and join in its filing.

**PREMISES CONSIDERED**, Petitioner prays

1. That this Petition be filed without cost bond pursuant to the provisions of Tenn. Code Ann. §§ 20-13-

101 and 47-18-116.

2. That the Assurance of Voluntary Compliance be approved and filed in accordance with the provisions of the Tennessee Consumer Protection Act.